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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,372	06/23/2003	Dany Berube	P038	1584

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EXAMINER

ADAMS, AMANDA S

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/602,372	Applicant(s) BERUBE ET AL.	
	Examiner Amanda Adams	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/19/04, 3/14/05, 1/23/05, 7/28/2005</u> | 6) <input type="checkbox"/> Other: _____ |

ASA

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: There are a few instances of improper grammar, such as in paragraphs 0006 lines 6-7, paragraph 0025 line 9, paragraph 0026 line 6, and paragraph 0027 line 9.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 4 recites the limitation "the ablation device" in the second line of the claim. However, said ablation device, while mentioned, is not claimed in Claim 1. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "about" does not clearly define the temperature range that is claimed by the applicant.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-6 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al (US 6,527,767).

7. Regarding claims 1-6, Wang et al disclose the invention substantially as claimed including:

- first and second jaw members with a clamping means for attaching the jaws together so that they can close upon a targeted tissue (column 5, lines 17-30),
- a partial lumen in the first jaw which can receive an ablation device (column 6, lines 18-28),
- a cross member for retaining the ablation device in appropriate position, defined as the areas in between the protrusions (figure 11A),
- a thermally isolating portion of the first jaw (column 8, lines 59-60),
- an inner surface adapted to receive the ablation device (figure 11A, [78]),
- and protrusions on the inner surface of the lumen (figure 11A, [64]).

Regarding claim 13, Wang et al discloses the invention substantially as claimed above that is allows the target tissue to be positioned between the jaw members so that

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energy applied to the ablation device will create an ablation lesion in the tissue (see citations above).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims ⁷~~6~~-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (US 6,527,767) in view of Hooven et al (US 6,517,536).

Wang et al disclose the invention substantially as claimed including a transmural system, but they fail to disclose a transmural system where the completion of an ablation lesion can be determined by at least two electrodes that can be used to measure one of a variety of electrical properties including impedance.

However, Hoover et al teach a transmural ablation device where the completion of an ablation can be determined (column 8, lines 59-62) and at least two electrodes are used to measure the impedance through the target tissue (column 8, lines 48-67).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a transmural device with an ablation monitoring system in the arms of a clamping device that contains an ablation device, in order to provide a feedback system for the surgeon.

Regarding claim 8, it would have been obvious to the device of Wang et al already contains electrodes [68], therefore it would have been obvious to combine the

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location of these electrodes with the function of transmitting and receiving electrical signals to determine the impedance of the ablated tissue, as described by Hoover et al.

As to claim 14, Wang et al disclose the method substantially as claimed except for failure to disclose a means for determining the transmuralty of an ablation lesion. However, Hoover et al teaches this as described above. Therefore it would have been obvious to have an ablation device capable of all that Wan et al's device can do plus this additional function from the device of Hoover et al.

10. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (US 6,527,767) in view of Hoover et al (US 6,517,536) and further in view of Francischelli et al (US 6,584,360).

Wang et al in view of Hoover et al disclose the invention substantially as claimed except for failure to disclose a liquid crystal color-changing thermometer. However, Francischelli et al teach a liquid crystal display device intended for use with tissue ablation systems that will either turn a color when a designated temperature is reached or that can change color when the temperature changes, so as to have a color gradient that corresponds to the temperature gradient (column 7, line 50-60).

As to claim 9, Wang et al has a passive transmuralty system as it provides no feedback to the surgeon.

Therefore, for claims 9-12, it would have been obvious to have a temperature sensing liquid crystal display on a clamp type ablation device, in order to provide the same temperature feedback that an ordinary ablation probe provides to the surgeon.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ASA

ASA 3/30/2006


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

4/2/06